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| APPLICATION NO.                                    | FILING DATE      | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                 | CONFIRMATION NO. |  |
|--|------------------|----------------------|-------------------------------------|------------------|--|
| 10/623,706   | 07/22/2003       | Ronald T. Sleeter    | T. Sleeter 1533.6100001/PAJ/KPQ 493 |                  |  |
| 26111 7590 11/09/2004                              |                  |                      | EXAMINER                            |                  |  |
| · · · · · · · · · · · · · · · · · · ·              | SSLER, GOLDSTEIN | THERKORN, ERNEST G   |                                     |                  |  |
| 1100 NEW YORK AVENUE, N.W.<br>WASHINGTON, DC 20005 |                  |                      | ART UNIT                            | PAPER NUMBER     |  |
|  |                  | 1723                 |                                     |                  |  |

DATE MAILED: 11/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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|   | Application No.   | Applicant(s)                    |  |  |  |  |
|---|---|---------------------------------|--|--|--|--|
|   | 10/623,706  | SLEETER ET AL.                  |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit                        |  |  |  |  |
|   | Ernest G. Therkorn  | 1723                            |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply  |   |                                 |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                                 |  |  |  |  |
| Status  |   |                                 |  |  |  |  |
| 1) Responsive to communication(s) filed on Jan. 1   | Responsive to communication(s) filed on <u>Jan.16&amp;Feb.5&amp;July19,2004</u> .   |                                 |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This  | action is non-final.  |                                 |  |  |  |  |
|   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |                                 |  |  |  |  |
| Disposition of Claims   |   |                                 |  |  |  |  |
| 4) ⊠ Claim(s) 1-22 is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 1-22 is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/o  | vn from consideration.  |                                 |  |  |  |  |
| Application Papers  |   |                                 |  |  |  |  |
| 9) ☐ The specification is objected to by the Examine  | r.  |                                 |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |   |                                 |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |                                 |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |                                 |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |                                 |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list  | s have been received. s have been received in Applicationity documents have been received in PCT Rule 17.2(a)).   | on No ed in this National Stage |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (RTO, 802)   | A) Intension Surrence   | /DTO 412\                       |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  4) Interview Summary (PTO-413) Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152) Paper No(s)/Mail Date  |   |                                 |  |  |  |  |

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sebedio (JAOCS 63:1541-1543, 1986) in view of Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993. At best, the claims differ from Sebedio (JAOCS 63:1541-1543, 1986) in reciting use of a silica column of at least 5 grams. Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993, pages 14, 27, 42, 48, and Table 4 discloses that use of a 5 or 10 gram column allows a higher flow rate and a larger syringe size and that use of a cartridge with too small a capacity causes poor or variable recovery. Millipore Manual No. PN011188 Table 2 (Silica) discloses that silica is a desirable packing material for lipid classification. It would have been obvious to use a silica column of at least 5 grams because Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993, pages 14, 27, 42, 48, and Table 4 discloses that use of a 5 or 10 gram column allows a higher flow rate and a larger syringe size and that use of a cartridge with too small a capacity causes poor or variable recovery and Millipore Manual No. PN011188 Table 2 (Silica) discloses that silica is a desirable packing material for lipid classification.

Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sebedio (JAOCS 63:1541-1543, 1986) in view of Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 as applied to claims 1-22 above, and further in view of

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Hamilton (Lipids 23:1146-1149, 1988). At best, the claims differ from Sebedio (JAOCS 63:1541-1543, 1986) in view of Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 in reciting rinsing residue. Hamilton (Lipids 23:1146-1149, 1988) (page 1148, column 2, the second full paragraph) discloses that washing allows the cartridge to be reused. It would have been obvious to rinse in Sebedio (JAOCS 63:1541-1543, 1986) in view of Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 because Hamilton (Lipids 23:1146-1149, 1988) (page 1148, column 2, the second full paragraph) discloses that washing allows the cartridge to be reused.

Claims 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sebedio (JAOCS 63:1541-1543, 1986) in view of Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 and Hamilton (Lipids 23:1146-1149, 1988) as applied to claims 9 and 19 above, and further in view of Snyder, Introduction to Modern Liquid Chromatography, 1979, page 715. At best, the claims differ from Sebedio (JAOCS 63:1541-1543, 1986) in view of Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 and Hamilton (Lipids 23:1146-1149, 1988) and Snyder, Introduction to Modern Liquid Chromatography, 1979, page 715 in reciting heating. Snyder, Introduction to Modern Liquid Chromatography, 1979, page 715 discloses that heating reduces sample retention. It would have been obvious to heat in Sebedio (JAOCS 63:1541-1543, 1986) in view of Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 and Hamilton (Lipids 23:1146-1149, 1988) because Snyder, Introduction to Modern Liquid Chromatography, 1979, page 715 discloses that heating reduces sample retention.

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Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sebedio (JAOCS 63:1541-1543, 1986) in view of Hamilton (Lipids 23:1146-1149, 1988) and Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993. At best, the claims differ from Sebedio (JAOCS 63:1541-1543, 1986) in reciting use of a silica column of at least 5 grams. Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993, pages 14, 27, 42, 48, and Table 4 discloses that use of a 5 or 10 gram column allows a higher flow rate and a larger syringe size and that use of a cartridge with too small a capacity causes poor or variable recovery. Millipore Manual No. PN011188 Table 2 (Silica) discloses that use of silica is a desirable packing material for lipid classification. Hamilton (Lipids 23:1146-1149, 1988) (page 1146, column 1, the second full paragraph) discloses that silica permits a 98% recovery of many lipids classes. It would have been obvious to use a silica column of at least 5 grams because Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993, pages 14, 27, 42, 48, and Table 4 discloses that use of a 5 or 10 gram column allows a higher flow rate and a larger syringe size and that use of a cartridge with too small a capacity causes poor or variable recovery, Millipore Manual No. PN011188 Table 2 (Silica) discloses that silica is a desirable packing material for lipid classification, and Hamilton (Lipids 23:1146-1149, 1988) (page 1146, column 1, the second full paragraph) discloses that use of silica permits a 98% recovery of many lipids classes.

Claims 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sebedio (JAOCS 63:1541-1543, 1986) in view of Hamilton (Lipids 23:1146-1149, 1988) and Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 as applied to

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claims 9 and 19 above, and further in view of Snyder, Introduction to Modern Liquid Chromatography, 1979, page 715. At best, the claims differ from Sebedio (JAOCS 63:1541-1543, 1986) in view of Hamilton (Lipids 23:1146-1149, 1988) and Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 in reciting heating. Snyder, Introduction to Modern Liquid Chromatography, 1979, page 715 discloses that heating reduces sample retention. It would have been obvious to heat in Sebedio (JAOCS 63:1541-1543, 1986) in Sebedio (JAOCS 63:1541-1543, 1986) in view of Hamilton (Lipids 23:1146-1149, 1988) and Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 because Snyder, Introduction to Modern Liquid Chromatography, 1979, page 715 discloses that heating reduces sample retention.

Any inquiry concerning this communication should be directed to E. Therkorn at telephone number (571) 272-1149. The official fax number is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernest G. Therkorn Primary Examiner Art Unit 1723

EGT November 5, 2004